

Amendments to the Drawings:

The attached new drawing sheet shows Figure 12, which illustrates a previously disclosed embodiment of a catheter that includes an ultrasonic imaging arrangement. This drawing sheet is to be included with the current set of drawing sheets.

Appendix: New drawing sheet for Figure 12

Remarks:

Applicants respectfully request reconsideration of the rejections set forth in the Final Office Action dated December 21, 2006. With this paper Applicants amend independent claims 25 and 36 to further recite features of the claimed invention. In particular, the claims now specify that the claimed thermal mapping system includes an ultrasonic imaging arrangement on or about the distal end of the elongated member, and the control circuitry receives and processes signals from the thermal sensor and the ultrasonic imaging arrangement to form a merged signal used to generate an image of a portion of the vessel wall. Claims 25-28 and 30-42 remain pending in this case. Applicants submit that the cited references do not disclose, teach, or suggest all of the limitations of the present claims and, as a result, the claims should be allowed.

In addition to the noted claim amendments, Applicants also address several formal matters the Examiner raised. The Examiner objected to the drawings as not showing the ultrasonic imaging arrangement feature of the claimed invention. Applicants submit herewith Figure 12 to illustrate a previously disclosed embodiment of the present invention that includes an ultrasonic imaging arrangement. As it illustrates an embodiment disclosed in the application as filed, Applicants add no new subject matter to the application. For example, Applicants disclosed a catheter of the present invention having an ultrasonic imaging arrangement in paragraph [0073] as filed. For clarity, Applicants currently amend this paragraph [0073] to specifically reference Figure 12. With the submission of Figure 12, Applicants submit that they have addressed the Examiner's objection to the drawings, and this objection should be withdrawn.

The Examiner rejected claims 29-32 and 41 under Section 112, first paragraph because, in the Examiner's view, the specification and drawings failed to "disclose the relative positioning of an

ultrasonic imaging arrangement including a rotatable ultrasonic imaging transducer coupled to a rotatable shaft in regards to the elongated member.” In response to this rejection, Applicants direct the Examiner’s attention to paragraph [0073] as originally filed. In this paragraph Applicants described an embodiment of the present invention that includes an ultrasonic imaging arrangement, making reference to “ultrasound catheter[s] such as that described by Yock, U.S. Pat. No. 4,794,931, No. 5,000,185, and No. 5,313,949 or that described by Maroney et al., U.S. Pat. No. 5,373,849, each of which are incorporated herein by reference,” and further noting that each of these ultrasound catheters “would work well” when implemented with the present invention. The Yock ‘931 patent, as one example, describes a catheter having an ultrasonic imaging arrangement and how the ultrasonic imaging arrangement may be oriented relative to the elongated member. Yock ‘931, col. 2, ll. 10-20; col. 3, l. 30 to col. 4, l. 57; Figures 1, 2, 3, and 49. Applicants are entitled to incorporate material by reference to U.S. patents, such as what Applicants did when filing the present application. MPEP 608.01(p). Here, for example, Yock ‘931 discloses an ultrasonic imaging arrangement that includes a rotatable ultrasonic imaging transducer coupled to a rotatable shaft, and further discloses a relative position of such an arrangement to the elongated member. Yock ‘931, col. 2, ll. 10-20; col. 3, l. 30 to col. 4, l. 57; Figures 1, 2, 3, and 49. Applicants therefore submit that the application as filed met the requirements of Section 112 through the incorporation by reference of teachings such as Yock ‘931, Yock ‘185, Yock ‘949, and Maroney ‘849. *See* MPEP 608.01(p); 37 C.F.R. § 1.57 (both expressly providing for incorporation by reference of material from U.S. patents).

Applicants now turn to the Examiner’s art-based rejections. As an initial matter, the Examiner rejected claim 25 as then-pending on the ground of nonstatutory obviousness-type double

patenting in view of claim 5 of U.S. Patent No. 6,256,026. With the current submission, Applicants amend claim 25 to recite, amongst other features, an ultrasonic imaging arrangement. As a result, Applicants submit that the nonstatutory obviousness-type double patenting rejection has been rendered moot and should be withdrawn.

Section 102 Rejections

Tachibana

The Examiner rejected claims 25-27 and 33-34 under Section 102(e) as anticipated by Tachibana U.S. Pat. No. 6,176,842. Applicants amend independent claim 25 (claims 26-27 and 33-34 are dependent therefrom) to include an ultrasonic imaging arrangement, and, further, to specify that the control unit receives, processes, and merges thermal and ultrasound signals from the thermal sensor and ultrasonic imaging arrangement, respectively, to generate an image of a portion of the vessel wall. Tachibana fails to disclose, teach, or suggest all of the limitations of independent claim 25 (and by extension dependent claims 26-27 and 33-34).

In contrast to the thermal imaging system presently claimed, Tachibana discloses “a kit and method for causing tissue death within a tissue site” that “includes a media with light activated drug activatable upon exposure to a particular level of ultrasound energy.” Tachibana, abstract. Unlike the presently-claimed invention, Tachibana does not utilize thermal and ultrasound signals to map a portion of a vessel wall. First, while Tachibana makes reference to the analysis of temperature, the Tachibana system utilizes temperature readings not as mapping or imaging data but, rather, as feedback control to monitor and adjust the power level of the energy supplied to the ultrasound transducers:

The temperature control signal is received by the power circuits 94. The power circuits 94 adjust the power level of the energy supplied to the ultrasound transducers 20 from the energy source 92. For instance, when the temperature control signal is above a particular level, the power supplied to a particular ultrasound transducer 20 is reduced in proportion to the magnitude of the temperature control signal.

Tachibana, col. 25, ll. 22-28. Neither in its discussion of the use of temperature control signals to adjust the power level of the energy supplied to the ultrasound transducers nor anywhere else in the specification does Tachibana make reference to analyzing thermal signals for graphic imaging purposes. Further, Tachibana does not disclose the use of ultrasound, coupled with thermal signals, as a method for imaging a vessel wall. To the extent Tachibana utilizes ultrasound, Tachibana employs controlled applications of ultrasound to activate the target drug. Tachibana, col. 8-9; col. 19, ll. 13-24; col. 22, ll. 17-19. Because Tachibana fails to disclose all of the limitations of the presently-claimed invention, the rejections based on Tachibana should be withdrawn.

Stern

The Examiner rejected claims 25-27 and 35 under Section 102(b) as anticipated by Stern U.S. Patent No. 5,443,470. Stern, like Tachibana, fails to disclose all of the limitations of the presently-claimed invention. With particular respect to Stern, the Examiner acknowledges that Stern “do[es] not disclose said system including an ultrasonic imaging arrangement.” As noted herein, Applicants amend independent claim 25 to include an ultrasonic imaging arrangement. Accordingly, Stern fails to disclose all of the limitations of these claims and these claims are not anticipated by Stern under Section 102(b).

Section 103 Rejections

Stern-Pomeranz Proposed Combination

The Examiner rejected claims 29-32 and 36-42 under Section 103(a) as unpatentable over a proposed combination of Stern and Pomeranz, U.S. Patent No. 5,558,093. Applicants submit that this proposed combination fails to disclose, teach, or suggest all of the limitations of these claims. In particular, Stern discloses an ablation catheter rather than an imaging or mapping catheter system. For example, to the extent Stern refers to the monitoring of heat, that monitoring is for the purpose of controlling the ablation of tissue, not mapping. Stern, col. 7, ll. 54-58; cols. 19-22. Additionally, the components illustrated in Figures 5 and 12 of Stern are simply a power source controller and switch matrix. Stern, col. 6, ll. 18-21; col. 7, ll. 54-58. That is, the Stern system utilizes these components to further its goal of tissue ablation and controlling of delivered heat to accomplish that goal. Nowhere does Stern disclose or suggest the use of temperature readings as a mapping or imaging tool. And unlike the presently-claimed invention, Stern fails to disclose or suggest a program or method to thermally image a vessel wall. As noted, the Examiner already acknowledged that Stern fails to disclose an ultrasonic imaging arrangement at all.

With the proposed combination of Stern and Pomeranz, the Examiner cited Pomeranz for a “teach[ing] of an ultrasonic imaging arrangement...” Pomeranz fails, however, to provide for all of the teachings missing from Stern. For example, while Pomeranz refers to ultrasonic imaging, nowhere does it disclose or suggest the combined use of ultrasound and thermal readings to image a vessel wall. Consequently, the proposed combination of Stern and Pomeranz does not disclose, teach, or suggest all of the limitations of claims 29-32 and 36-42. Stern is not directed to graphic imaging using thermal signals and Pomeranz fails to disclose or suggest using both ultrasound and

thermal signals for graphic imaging of a vessel wall. The Section 103(a) rejection based on this proposed combination should therefore be withdrawn.

Stern-vanHooydonk Proposed Combination

The Examiner rejected claim 28 under Section 103(a) as unpatentable over a proposed combination of vanHooydonk U.S. Patent No. 5,902,251 and Stern. The Examiner acknowledged that Stern does “not disclose said display shows a color coded thermal map,” and therefore cited vanHooydonk as “disclos[ing] an analogous apparatus comprising a display that graphically displays a thermal map from thermal sensors color coded such that temperature of tissue is indicated by the color on the display...” Applicants submit that the claims are patentable over this proposed combination because, like Pomeranz, vanHooydonk fails to provide for the limitations from the currently-pending claims that are missing from Stern. The vanHooydonk system utilizes electromagnetic radiation for ablation. In this context, the vanHooydonk system processes temperature readings to trigger alarms based on those readings and to enable a user to monitor temperature levels to modulate the level of electromagnetic radiation delivered to a tissue. vanHooydonk, col. 16, ll. 2-19. VanHooydonk does not disclose or suggest the use of temperature readings to map or image a vessel wall. Further, to the extent vanHooydonk graphically displays temperature readings, it does so by presenting a temperature profile around the electromagnetic radiation applicator. vanHooydonk, col. 16, ll. 42-45; Figure 8B. Such a profile display is localized to the applicator and not with specific reference to the vessel wall. The invention presently claimed in independent claim 25 and its dependent claims (such as claim 28), in contrast, graphically displays a thermal map of the vessel wall. VanHooydonk fails to disclose or suggest this feature.

Favorable action on the merits of the claims is earnestly solicited. If any issues remain, please contact Applicants' undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,

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Dated: _____

4/19/07

By: _____



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